DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
Facsimile: 504-253-4520

December 1, 2004

WARNING LETTER NO. 2005-NOL-05

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Lloyd B. Bearden, Jr.
Owner/President
Bearden Sandwich Co., Inc.
d.b.a. Southern Belle Sandwich Co.
1969 Lobdell Boulevard
Baton Rouge, Louisiana 70806

Dear Mr. Bearden:

On October 4 and 15, 2004, a United States Food and Drug Administration (FDA) investigator inspected your firm, located at 2267 South Forbes Drive, Montgomery, Alabama. We found you have serious deviations from the Seafood Hazard Analysis Critical Control Point (HACCP) regulation, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan complying with this section, or otherwise operating in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your tuna salad sandwiches are adulterated, as the sandwiches have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulation through links in FDA's home page at www.fda.gov.

Your deviations are as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards reasonably likely to occur, and you must have a written HACCP plan to control any food safety hazards reasonably likely to occur to comply with 21 CFR 123.6(a) and (b). However, your firm does not have a HACCP plan for tuna salad sandwiches to control the food safety hazard of scombrotoxin (histamine) formation and pathogen growth from time/temperature abuse.

2. You must maintain sanitation control records which, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However, your firm does not maintain

sanitation control records for the safety of water coming into contact with food or food contact surfaces; condition and cleanliness of food contact surfaces; prevention of cross-contamination; maintenance of hand washing, hand sanitizing, and toilet facilities; protection of food, food packaging material, and food contact surfaces from adulteration with contaminants; proper labeling, storage, and use of toxic compounds; control of employee health conditions, which could result in microbiological contamination; and, exclusion of pests from the facility. All are required for the processing of your tuna salad sandwiches.

The deficiencies observed during the current inspection were brought to your attention in our letter dated September 26, 2003, following an inspection conducted on July 18 – August 1, 2003. At that time, [redacted] responded to our letter, stating product is not stored at the inspected facility with the exception of unusual circumstances of equipment failure. FDA is concerned you have not taken action to correct your firm's deficiencies. Tuna salad sandwiches are being stored at the inspected facility, even though your response stated sandwiches would not be stored at this location.

We may take further action if you do not correct these violations promptly. For instance, we may take further action to seize your product and/or enjoin your firm from operating.

You must respond in writing, within 15 working days from your receipt of this letter, outlining the specific things you are doing to correct these deviations. You should include in your response documentation, such as HACCP and sanitation monitoring records, or other useful information to assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you to explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring your processing plant operates in compliance with the Act, the Seafood HACCP regulation, and the Current Good Manufacturing Practice regulation, 21 CFR 110. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your response to the United States Food and Drug Administration, New Orleans District, Attention: Cynthia R. Crocker, Compliance Officer, 100 W. Capitol Street, Suite 340, Jackson, Mississippi 39269. If you have questions regarding any issue in this letter, please contact Ms. Crocker at (601) 965-4581, extension 106.

Sincerely,

H. Tyler Thornburg
District Director
New Orleans District

Enclosure: Form FDA 483
21 CFR 110 & 123